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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,678	02/06/2004	James G. Karras	23546-09725US (Client No.	7514

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,678	KARRAS, JAMES G.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/27/05, 6/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of group I, claims 1-13, and SEQ ID NO: 342, in the reply filed on 7/14/2005 is acknowledged.

Claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences on page 118 of the specification that do not contain a SEQ ID NO.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instance of failure to comply is not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the instant case, the effective filing date of the instant claims is determined to be that of the instant application 10/773,678, which has an effective filing date of 2/6/2004. The instant case 10/773,678 does not receive the benefit of application 10/713,139 or earlier because the instantly recited antisense oligonucleotide, SEQ ID NO: 342, is not disclosed in the specification or claims of the priority applications. Thus, the instant application 10/773,678 is accorded an effective filing date of 2/6/2004.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Karras (US 6,159,694).

The instant invention is drawn to an antisense compound 20 to 30 nucleobases in length targeted to a nucleic acid molecule encoding human STAT3, wherein said antisense compound comprises at least an 8 nucleobase portion of SEQ ID NO: 342, wherein said antisense compound inhibits the expression of human STAT3. The antisense compound is specified to be an antisense oligonucleotide comprising a phosphorothioate linkage, a 2'-O-methoxyethyl moiety, or a 5-methylcytosine modified nucleobase. The invention is further drawn to a chimeric oligonucleotide and to a pharmaceutical composition comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier. The pharmaceutical composition further comprises a colloidal dispersion system.

Karras teaches a 20 nucleotide antisense oligonucleotide targeted to a nucleic acid molecule encoding STAT3, wherein said antisense oligonucleotide comprises a 14 nucleobase portion of instant SEQ ID NO: 342 (see nucleotides 7-20 of SEQ ID NO: 19 of Karras which are 100% identical to nucleotides 1-14 of instant SEQ ID NO: 342). Karras teaches modifications such as phosphorothioates, 2'-O-methoxyethyl moieties, and 5-methylcytosine modified nucleobases (see claims 3-8). Karras teaches chimeric oligonucleotides and pharmaceutical compositions comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier or diluent (see claims 9 and 10). Karras teaches pharmaceutical compositions further comprising a colloidal dispersion system (see claim 11). Karras teaches specific targeting and inhibition of STAT3 expression.

Therefore, the instant invention is anticipated by Karras.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US 6,248,586 B1).

The instant invention is drawn to an antisense compound 20 to 30 nucleobases in length targeted to a nucleic acid molecule encoding human STAT3, wherein said antisense compound comprises at least an 8 nucleobase portion of SEQ ID NO: 342, wherein said antisense compound inhibits the expression of human STAT3. The antisense compound is specified to be an antisense oligonucleotide comprising a phosphorothioate linkage, a 2'-O-methoxyethyl moiety, or a 5-methylcytosine modified nucleobase. The invention is further drawn to a chimeric oligonucleotide and to a pharmaceutical composition comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier. The pharmaceutical composition further comprises a colloidal dispersion system.

Monia et al. teach a 20 nucleotide antisense oligonucleotide, wherein said antisense oligonucleotide comprises a 9 nucleobase portion of instant SEQ ID NO: 342 (see nucleotides 2-10 of SEQ ID NO: 27 of Monia et al. which are 100% identical to nucleotides 5-13 of instant SEQ ID NO: 342). Monia et al. teach modifications such as phosphorothioates, 2'-O-methoxyethyl moieties, and 5-methylcytosine modified nucleobases (see claims 4-9). Monia et al. teach chimeric oligonucleotides and pharmaceutical compositions comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier or diluent (see claims 10 and 11). Monia et al. teaches pharmaceutical compositions further comprising a colloidal dispersion system

(see claim 12). Although the antisense oligonucleotide taught by Monia et al. is not disclosed as being targeted to a nucleic acid molecule encoding human STAT3 or inhibiting STAT3 expression, the antisense oligonucleotide taught by Monia et al. meets the structural limitations of the instant claims and is therefore necessarily considered to function as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, the instant invention is anticipated by Monia et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of double patenting over claims 1-12 of U. S. Patent No. 6,159,694 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming

common subject matter, as follows: The instant claims are drawn to an antisense compound 20 to 30 nucleobases in length targeted to a nucleic acid molecule encoding human STAT3, wherein said antisense compound comprises at least an 8 nucleobase portion of SEQ ID NO: 342, wherein said antisense compound inhibits the expression of human STAT3. The antisense compound is specified to be an antisense oligonucleotide comprising a phosphorothioate linkage, a 2'-O-methoxyethyl moiety, or a 5-methylcytosine modified nucleobase. The invention is further drawn to a chimeric oligonucleotide and to a pharmaceutical composition comprising the antisense oligonucleotide and a pharmaceutically acceptable carrier. The pharmaceutical composition further comprises a colloidal dispersion system.

Patent '694 recites an antisense compound 8 to 30 nucleobases in length targeted to nucleobases 224-2503 of a coding region of human STAT3, wherein said antisense compound inhibits the expression of human STAT3 (see claim 1). Patent '694 specifically teaches an antisense oligonucleotide 20 nucleobases in length comprising a 14 nucleobase portion of instantly claimed SEQ ID NO: 342 (see nucleotides 7-20 of SEQ ID NO: 19 of Patent '694 which are 100% identical to nucleotides 1-14 of instant SEQ ID NO: 342). Claim 1 of Patent '694 encompasses an oligonucleotide meeting each of the limitations of instant claim 1. Patent '694 teaches that the antisense compound is an antisense oligonucleotide, wherein the oligonucleotide comprises a phosphorothioate modification, a 2'-O-methoxyethyl moiety, or a 5-methylcytosine modified nucleobase (see claims 3-8). Patent '694 teaches chimeric oligonucleotides and pharmaceutical compositions comprising the antisense

oligonucleotide and a pharmaceutically acceptable carrier or diluent (see claims 9 and 10). Patent '694 teaches pharmaceutical compositions further comprising a colloidal dispersion system (see claim 11). Therefore, the claims of patent '694 encompass an embodiment that meets the structural limitations of the instant claims.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Allowable Subject Matter

Claim 13 is allowed because it is considered free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

J.D. SCHULTZ, Ph.D.
PATENT EXAMINER